

### **Amendments to the Specification**

Please replace the paragraph beginning at page 1, line 4 with the following amended paragraph:

This application is being filed concurrently with the following six commonly assigned patent applications: "Cartridge and Pump with Axial Loading," (~~also identified by Attorney Docket No. 9015.0143US01 and Express Mail Certificate No. EV036305619US~~); United States Patent Application Serial No. 10/086,646, "Syringe Pump Control Systems and Methods," (~~also identified by Attorney Docket No. 9015.144US01 and Express Mail Certificate No. EV036305622US~~); United States Patent Application Serial No. 10/086,994, "Child Safety Cap for Syringe Pump," (~~also identified by Attorney Docket No. 9015.145US01 and Express Mail Certificate No. EV036305636US~~); United States Patent Application Serial No. 10/086,993, "Programmable Medical Infusion Pump," (~~also identified by Attorney Docket No. 9015.141US01 and Express Mail Certificate No. EV036305605US~~); and United States Patent Application Serial No. 10/087,449, "Programmable Medical Infusion Pump Displaying a Banner," (~~also identified by Attorney Docket No. 9015.147US01 and Express Mail Certificate No. EV036305579US~~); United States Patent Application Serial No. 10/087,205, "Programmable Insulin Pump," (~~also identified by Attorney Docket No. 9015.148US01 and Express Mail Certificate No. EV036305582US~~); United States Patent Application No. 10/086,641. The disclosures of these six patent applications are hereby incorporated herein by reference in their entirety.

Please replace the paragraph beginning at page 2, line 2 with the following amended paragraph:

A large portion of the world's population suffers from diabetes. Many of these people need to take injections of insulin to normalize the level of sugar in their bodies to

prevent complications. Such complications can include kidney failure, loss of circulation, and blindness. The need to manually take injections with a syringe and the process of determining the dose for various shots can be a great inconvenience and can limit a diabetic's activities and restrict their movements. Furthermore, it can be difficult to maintain a consistent level of blood glucose because there is a practical limit to the number of injections that most ~~patient's~~ patients can receive.

Please replace the paragraph beginning at page 6, line 10 with the following amended paragraph:

Additionally, the pump generates and presents information and fields in user interfaces, which are also referred to as displays. The user interfaces can include fields, alpha/numeric character strings, times, and dates. The fields, also referred to as cells, prompt users to enter ~~and-or~~ and/or select information. Because there is not an alpha/numeric keyboard on the pump, each of the field[[s]] is associated with a spin box that includes values the user can enter into the field. The user spins or scrolls through values until the desired value is visible within the field. When the user selects the visible value it is entered into the field. The user selects a value with a Next function, Edit function, or Select function as identified herein. When the pump displays a field and the field has focus, it is said to prompt the user to select a value. Additionally, selecting a value in a field causes the pump to index focus to the next field as defined by the programmed operations or to display the next user interface as defined by the programmed operations. In an alternative embodiment, the pump has an alpha/numeric keyboard from which operating parameters can be typed directly into the pump.

Please replace the paragraph beginning at page 7, line 1 with the following amended paragraph:

The description set forth herein ~~discussed~~ discusses pumping insulin. One skilled in the art will realize that many of the features, structures, and methods disclosed herein can be used with medical infusion pumps for delivering agents other than insulin. The term "user" generally applies ~~o~~ to the person who is receiving insulin from the pump. In many contexts, however, the user could also refer to any other person such as a caregiver that is operating the pump.

Please replace the paragraph beginning at page 7, line 13 with the following amended paragraph:

The pump motor 104 drives a drive mechanism 112 that pushes a plunger mechanism 114. The plunger mechanism 114 ejects insulin from an insulin cartridge (not shown). The insulin cartridge contains a supply of insulin for delivery to a patient. These mechanical components are illustrated and discussed in commonly assigned United States patent application serial no.                      ~~(also identified by attorney docket no. 9015-143US01)~~, 10/086,646, entitled Cartridge and Pump With Axial Loading, the disclosure of which was hereby incorporated by reference above.

Please replace the paragraph beginning at page 8, line 6 with the following amended paragraph:

The microprocessor 102 is in electrical communication with both a random access memory (RAM) 116 and a read only memory (ROM) 118, which are onboard the pump 100 but external to the microprocessor 102 itself. In one possible embodiment, the microprocessor 102 includes internal memory as well. The RAM 116 is a static RAM that stores data that can change over time such as pump settings and a historical log of events experienced by the insulin pump 100. The ROM 118 stores code for the operating system and the application programs. The ROM 118 can be any type of programmable ROM such as an EPROM. In one possible embodiment, the RAM 116 has 500 kilobytes of memory capacity and the ROM 118 has 2 megabytes of memory capacity.

Please replace the paragraph beginning at page 8, line 15 with the following amended paragraph:

An infrared (IR) port 120 is in electrical communication with the microprocessor. As explained in more detail below, the IR port 120 provides data communication with an external device such as a computer for programming an application program, programming pump settings, and downloading historical data logs. The insulin pump 100 can include other types of communication ports in place of or in addition to the IR port 120. Examples of other possible communication ports include a radio frequency (RF) port or a port that provides a hard-wired data communication link such as an RS-232 port, a USB port, or the like.

Please replace the paragraph beginning at page 9, line 13 with the following amended paragraph:

Other inputs into the microprocessor 102 is include a pressure sensor 126, which is sensitive to the pressure within a reservoir of insulin; a cartridge sensor 128, which is sensitive to the presence of an insulin cartridge; and a motion detector 130, which detects motion of a gear (not shown) in the drive mechanism 112. The pressure sensor 126, cartridge sensor 128, and motion detector 130 are described in more detail in United States Patent application serial number \_\_\_\_\_ ~~(also identified by attorney docket number 9014.143US01),~~ 10/086,646, which is entitled Cartridge and Pump With Axial Loading, the disclosure of which was incorporated by reference above.

Please replace the paragraph beginning at page 10, line 22 with the following amended paragraph:

The application program presents a home page 152 in the display portion 134 of the screen 106. The home page 152 includes a first icon 154 that illustrates the amount of insulin remaining in the insulin cartridge. This first icon 154 has the shape of a syringe and a bar 156 arranged relative to the syringe shape to illustrate the amount of remaining

insulin. The amount of remaining insulin also is quantified and listed below the first icon 154. A second icon 158 has the shape of a battery and has a bar 160 arranged relative to the battery-shape to illustrate the amount of remaining battery life. The percentage of remaining life on the battery is positioned below the second icon 158.

Please replace the paragraph beginning at page 12, line 19 with the following amended paragraph:

In the example set forth in Figure 3, the pump 100 has an active temporary rate delivery program so the pump 100 prompts the user to select whether to suspend all active delivery programs or just the temporary rate delivery program by scrolling to the desired delivery program to suspend, ~~and activating~~ The user then activates a Select function 194, which is assigned to the second function key 140.:

Please replace the paragraph beginning at page 13, line 1 with the following amended paragraph:

After the user activates the Select function 194, the insulin pump 100 prompts 176 the user to confirm suspension of the selected delivery, whether it is all delivery, the extended bolus, the combination bolus, or the temporary rate. The user can confirm the suspend operation by activating the yes function 178 by pressing the second function key 140 or cancel the suspend operation by activating the no function 180 by pressing the first function key 138. If there is no insulin being delivered in addition to the standard basal rate, the insulin pump will automatically skip from the home page 152 to the prompt 176 asking the user to confirm suspension of the ~~all~~-delivery.

Please replace the paragraph beginning at page 15, line 1 with the following amended paragraph:

Accessing the cartridge is discussed in more detail in United States patent application serial no. \_\_\_\_\_ ~~(also identified by attorney docket no.~~

9014.143US01), 10/086,646, entitled Cartridge and Pump With Axial Loading, the disclosure of which was incorporated by reference above.

Please replace the paragraph beginning at page 19, line 4 with the following amended paragraph:

The pump 100 then indexes focus to a duration field 236 in which the user sets the duration between the triggering event and when the glucose reminder signals an alert. The user scrolls to and selects the desired duration. In one possible embodiment, the user scrolls through values in the range from 1 hour to 5 hours in a predetermined increment, such as 15 minute, half hour[[s]], or one hour increments. The pump 100 then indexes focus to an automatic-off field 238. If the user selects no in the glucose-reminder field 234, the pump 100 will skip over the duration field 236 and index focus directly to the automatic-off field 238.

Please replace the paragraph beginning at page 24, line 15 with the following amended paragraphs:

- (4) The 500-Rule factor, which is used to estimate the grams of carbohydrates that are covered by each unit of insulin. To determine the grams of carbohydrates that are covered by each unit of insulin, the 500-Rule factor is divided by the total daily dose of insulin required to maintain the user blood sugar level in an acceptable range. The typical 500-Rule factor is 500, and hence the ratio is called the 500 Rule. However, the factor may vary for different types of insulin and from user to user and the value for the 500-Rule factor is calculated and stored. In one possible embodiment, the 500-Rule factor is stored as a daily value depending on the total delivery dose and an average value for a predetermined number of days. In an alternative embodiment, the 500-Rule factor is not stored but is

calculated as the 500-Rule factor is required for a display, calculation, or other function.

- \_\_\_\_\_ (5) The 1800-Rule factor, which is used to estimate the number of units of insulin is required for each mg/dL (or mmol/L) drop in blood glucose. To determine the drop in blood glucose for each unit-~~if~~ of insulin delivered to the user, the 1800-Rule factor is divided by the total daily dose of insulin required to maintain the user blood sugar level in an acceptable range. The typical 1800-Rule factor is 1800, and hence the ratio is called the 1800 Rule. However, the factor may vary for different types of insulin and from user to user and the value for the 1800-Rule factor is calculated and stored. In one possible embodiment, the 1800-Rule factor is stored as a daily value depending on the total delivery dose and an average value for a predetermined number of days. In an alternative embodiment, the 1800-Rule factor is not stored but is calculated as the 1800-Rule factor is required for a display, calculation, or other function.

Please replace the paragraph beginning at page 27, line 12 with the following amended paragraph:

Upon selecting the yes or no value in the average-delivery-summary field 266, focus indexes to ~~[[a]]~~ basal-as-percent-of-TDD field 268. In one possible embodiment, basal as a percent of TDD is the amount of insulin delivered by the pump 100 according to a basal protocol as a daily percent of the total insulin delivered by the pump 100. The user selects whether to display the Basal as a Percent of TDD menu item in the History submenu 290 using a procedure similar to that described for the Delivery Summary. Under this menu item, the pump 100 lists the total daily amount of insulin delivered as a basal as a percent of the total daily dose of insulin ~~[[delivered-]]~~ In an alternative embodiment, the pump 100 lists the total daily amount of insulin delivered as a bolus as a percent of the total daily dose of insulin delivered. In various embodiments, the bolus as a percent can be listed as the meal bolus as a percent of the total daily dose of insulin

delivered, correction bolus as a percent of the total daily dose of insulin delivered, or total bolus as a percent of the total daily dose of insulin delivered. The pump 100 then indexes focus to an average-basal-as-percent-of-TDD field 270. In one possible embodiment, average basal as a percent of total daily delivery (TDD) is the amount of insulin delivered by the pump 100 according to a basal protocol as an average daily percent over a predetermined number of days of the total insulin delivered by the pump 100. The user selects whether to display the Avg Basal as a Percent of TDD menu item in the History submenu 290 using a procedure similar to that described for the Delivery Summary. The pump 100 lists the average basal as a percent of the total daily delivery under this menu item.

Please replace the paragraph beginning at page 30, line 12 with the following amended paragraph:

In other embodiments, the pump calculates the average correction factor for periods other than 7 days. For example, the range could be in the range from 2 to 90 days. In another possible embodiment, the pump 100 calculate[[s]] the average correction factor for however number of days it stores historical data. In yet another embodiment, the user can select a predetermined number of days over which to calculate and average the correction factor.

Please replace the paragraph beginning at page 31, line 10 with the following amended paragraph:

If the user selects Delivery Summary, the pump indexes to a Delivery Summary 292 that has a date field 294 in which the current date is listed and a Total field in which the total number of insulin units delivered is listed, a Meal Bolus field in which the number of insulin units delivered as a meal bolus is listed, a Carbs field in which the total number of carbohydrates that the user entered as an estimate of carbohydrate consumption is listed, Corr. Bolus field in which the total number of insulin units



delivered as a correction bolus are listed, and a Basal field in which the total number of insulin units delivered according to the basal protocols employed by the pump are listed.

Please replace the paragraph beginning at page 37, line 4 with the following amended paragraph:

In an alternative embodiment, ~~with in~~ within the display entitled "My Program X," the user can access a spin box in which they scroll through a list of optional names and select a custom name for the enabled basal delivery programs. The selected name would then replace the generic name (e.g., Basal 1, Basal 2, Basal 3, and Basal 4 in the illustrated example) for the program associated with the display. Examples of optional names that might be loaded in the pump 100 include weekday, weekend, sick, and monthly (which is to designate a basal delivery program set for a woman's menstrual cycle).

Please replace the paragraph beginning at page 39, line 12 with the following amended paragraph:

In one possible embodiment, the first time interval 330 always starts at 12:00 midnight. In this embodiment, the last time interval will terminate at 12:00 midnight. If, within the Summary Display 324, the user highlights and selects the first time interval 330 for editing, the pump 100 indexes to the Edit display 336 and initially highlights the delivery rate 328 for the first time interval 330 rather than the start time 326. In ~~other~~ another embodiment, however, the user can change the start time 320 for the first time interval 330. The last time interval would then extend until the start time for the first time interval 330. Additionally, within the Summary Display 324, the user can scroll to a delivery interval other than the first interval 330 and activate the Edit function 254. In this situation, the start-time field 342 for the selected interval is initially placed into focus rather than the delivery-rate field 340.

Please replace the paragraph beginning at page 42, line 5 with the following amended paragraph:

When focus is on the give-reminder field 354, the user scrolls to and selects either a yes value or a no value. Selecting the yes value enables a temporary-rate reminder (either audible or vibratory) that ~~that~~ is periodically generated while the pump 100 is delivering a temporary rate. Focus then indexes to an interval field 356 in which the user scrolls to and selects an interval that sets how frequently the pump 100 gives a reminder. In one possible embodiment, the user scrolls between 5 minutes and 1 hour in increments such as 5 minutes, 10 minutes, or 15 minutes. Upon selection of the interval, focus indexes to an end-temporary-rate-reminder field 358. Selecting the no value in the give-reminder field 358 disables the temporary-rate reminder and indexes focus directly from the give-reminder field 354 to the end-temporary-rate-reminder field 358.

Please replace the paragraph beginning at page 43, line 1 with the following amended paragraph:

The pump 100 next indexes focus to a review/edit-custom-temporary-rate field 360. The user scrolls to and selects either a yes value or a no value. If the user selects the no value, the pump returns to the Personalize Delivery submenu 302. If the user selects the yes value, the pump indexes to a display 362 entitled "Custom Temp Rate" and lists the name 364 of each customized temporary rate delivery program and displays a check box 366 next to each name 364. In one possible embodiment, there are four separate temporary rate programs. If a customized temporary rate program is enabled, the check box 366 for that delivery program is set. If a customized temporary rate program is disabled, the check box 366 for that temporary rate delivery program is cleared. When a customized temporary rate delivery program is enabled, it is displayed in the Temporary Basal Rates submenu 376 (Figure [[+]] 16) as described below and the user can then selectively execute the temporary rate delivery program through the Temporary Rates submenu 376. If the customized temporary rate delivery program is not

enabled, it is not displayed in the Temporary Rates submenu 376 as described below and it cannot be executed.

Please replace the paragraph beginning at page 46, line 1 with the following amended paragraph:

The edit screen 379 has a duration field 378 that contains the duration for the temporary rate and a rate field 380 that contain[[s]] data to set the temporary rate. If the temporary rate is one that was customized as described in conjunction with Figure 15, the duration field 378 contain[[s]] the duration as it was initially set in the "Custom Temp Rate: Temp Rate X" display 367. Similarly, the rate field 380 initially contains the rate data originally set in the "Custom Temp Rate: Temp Rate X" display 367. The user can then adjust these values by using the scroll keys to change the values and the Next function to index from the duration field 378 to the rate field 380. In one possible embodiment, for example, the duration can be set in the range from 0 minutes to 72 hours, and the rate can be set in the range from about 0% to about 400% if percent is the rate factor (or from a rate of 0 units per hour to the maximum basal rate if the units per hour is the rate factor).

Please replace the paragraph beginning at page 55, line 21 with the following amended paragraph:

If the pump 100 is programmed to enable administration of a correction bolus through the Meal Bolus program, the pump 100 prompts 436 the user to enter the number of units to deliver as a meal bolus. The user then activates the Deliver function 384 and the pump 100 prompts 438 the user to enter the amount by which they want to lower their blood glucose level. In one possible embodiment, the user enters the amount by scrolling through values in units of either mg/dL or mmol/L. When the desired drop in blood glucose is entered, the user activates the Next function 200, which causes the pump 100 to calculate a recommended bolus amount and to display a user interface with the banner 439 stating "Bolus to Lower BG X plus Y meal bolus." X is the amount by which the

user entered to lower the blood glucose level, and Y is the amount of the meal bolus entered by the user.

Please replace the paragraph beginning at page 67, line 17 with the following amended paragraph:

In an alternative embodiment, when the pump 100 is programmed to enable administration of a correction bolus through a Meal Bolus, the pump 100 prompts the user to enter their current blood glucose measurement. The pump 100 calculates the current correction factor and displays the correction factor in the user interface. The pump 100 also displays the target blood glucose level. The user then enters his or her current blood glucose level in units of either mg/dL or mmol/L, by scrolling through a range of values until the current blood glucose level is displayed. In this embodiment, the target blood glucose level and the appropriate units are programmed into the pump 100 when personalizing the correction bolus program. Once the user enters the current blood glucose level, the user activates the Next function 200 and the pump 100 calculates a ~~recommend~~ recommended bolus amount and adds it to the meal bolus. The pump 100 displays the user interface with the banner "Bolus to Lower BG X plus Y Meal Bolus." The user can then change the amount and activate the Deliver function 384 to begin delivery of the bolus as described above.

Please replace the paragraph beginning at page 69, line 3 with the following amended paragraph:

Referring to Figure 26, delivery of a combination bolus is programmed into the pump in a manner similar to that of an extended bolus. However, the pump also prompts 498 the user to enter the proportion or percent of the bolus that the pump 100 delivers immediately upon activation of the Deliver function 384. To enter the proportion of the amount that is delivered immediately, the user scrolls through percentages until the desired percentage of the bolus for immediate delivery is set. In one possible embodiment, the user scrolls through percentages in the range from 0% to 100% in

increments of 1. Additionally when programming the pump to deliver a combination bolus, the pump 100 displays 500 the percentage of the bolus that is to be delivered immediately in the confirmation user interface 488. In an alternative embodiment, the user enters the proportion or percent of the bolus that the pump 100 delivers over an extended period.

Please replace the paragraph beginning at page 71, line 3 with the following amended paragraph:

In an example, if the increment count is set at .5 units and the user desires to program a standard meal bolus of 2 units, the user would press the audio bolus once to initiate programming the standard meal bolus and then four more times to increment the bolus amount to 2 units. After the fourth button ~~is push~~ pushed, the user pauses and the audible-button timer times out. The pump 100 then generates a series of four beeps to signal that the bolus amount was incremented four times and a final beep to signal completion of the series of beeps. The countdown time would then begin to run, and the pump 100 would deliver a meal bolus of 2 units when the countdown timer times out.

Please replace the paragraph beginning at page 78, line 8 with the following amended paragraph:

The third panel 580 presents instructions to the user. In one possible embodiment, the user interface presents a help label 582 (e.g., the question mark in the illustrated example) in each of the group boxes 549, 564, and 570. When the user clicks on a help label 582, instructions specific to the group box or other ~~aspect~~ aspects of the user interface associated with the help label are presented in the third panel. Alternatively, the user can point to a particular aspect of the user interface and right click on the mouse to present field-specific instructions in the third panel.

Please replace the paragraph beginning at page 84, line 9 with the following amended paragraph:

Within the temporary rate table 660, each row has six cells. The first cell 670 has a check box 672. To enable the temporary rate defined by that row, the user sets the check box 672. The second cell 674 has a text field in which the user types a name to identify the temporary rate defined by that row. Examples might include exercise, 5-mile run, sick, evening, and the like. The third cell 676 is a text field to set the temporary rate to be programmed as a percent of current basal rate or as a new rate. In one possible embodiment a spin is present in the third cell 676 when focus is placed on the cell. The user can then spin box through the types of temporary rates (e.g., % of Basal or New Rate) and set the desired type.

Please replace the paragraph beginning at page 85, line 16 with the following amended paragraph:

For example, Figure 30E illustrates the fifth primary window 544e, which is for setting the banner displayed in the home page 152 of the pump 100. Primary window 544e is in the stack of primary windows 544. The fifth primary window 544e includes two panels. The first panel 690 has a field check box 692 and a text field 694 mated to the checkbox 692. To enter text into the home page 152, the ~~use~~user sets the checkbox 692 and enters text (numbers and letters as desired) into the text field 694. If the pump 100 includes multiple home pages 152 through which the user can scroll, an embodiment of the primary window 544e includes a checkbox 692 and mating text field 694 for each of the home pages 152. The user can then designate certain text for a particular home page 152 by setting the checkbox 692 associated with that home page 152 and entering text into the mating text field 694. In an alternative embodiment, if the text in the text field 694 is too long to fit into one display, the pump 100 automatically generates multiple home pages 152 through which the user can scroll and divides the text from the text field 694 between the multiple home pages 152. In another embodiment, similar text fields and associated checkboxes can be used to customize displays and messages for particular alarms, alerts, and reminders.

Please replace the paragraph beginning at page 86, line 12 with the following amended paragraph:

Yet other embodiments of the user interface 542 ~~includes~~ include various windows, buttons, checkboxes, spin boxes, and fields for setting other parameters used to operate the pump 100. Examples of such other parameters that can be set through the user interface 542 include various format settings, alarms, reminders, operating limits, report formats, security settings, character strings, and indeed any other operating parameters, data, settings, and character strings that can be programmed into the pump 100.